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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,909	02/14/2000	ANNIE MEINIEL	065691/0179	5643

22428 7590 05/20/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,909

Applicant(s)

MEINIEL ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,11,13,16,17,20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,11,13,16,17,20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2004 has been entered.

Response to Amendment

2. Claims 1-6, 11 and 20 have been amended and claims 9-10, 12, 14-15, 18-19, 21 and 23 have been cancelled as requested in the amendment of Paper filed on March 22, 2004. Claims 1-6, 8, 11, 13, 16-17, 20 and 22 are pending in the instant application.

3. Applicant elected with traverse Group III in Paper No. 12 and SEQ ID NO: 7 as a single molecular embodiment for examination in Paper No. 16. Additionally, because a peptide of SEQ ID NO: 8 is a representative sequence that encompasses SEQ ID NO: 7, the claims that include SEQ ID NO: 8 are also included in the examination.

Claims 1-6, 8, 11, 13, 16, 17, 20 and 22, in so far as they are directed to peptides of SEQ ID NO: 7 and 8 are under examination in the instant office action.

4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed on November 24, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

7. Claim 16 stands rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons of record in section 7 of Paper No. 18 and section 8 of Paper No. 22. Applicant is advised that the peptide recited in claim 16 is not limited to "no more than 26 contiguous amino acids" (middle at page 10 of the Response filed November 24, 2003). Claim 16 encompasses "a peptide having at least the following amino acid sequence [...] (SEQ ID NO: 8)". Thus, the claimed subject matter encompasses molecular embodiments comprising SEQ ID NO: 8, which includes naturally occurring proteins.

Claim Rejections - 35 USC § 112

8. Claims 8, 11, 17 and 20 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement for reasons of record as applied to claims 17 and 20 in section 11 of Paper No. 18 and in section 10 of Paper No. 22. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 8 and 17 are directed to a pharmaceutical composition comprising a peptide of SEQ ID NO: 8 and claims 11 and 20 are directed to a method for treating a pathological condition or trauma such as neuroblastoma or neural injury by administration to a patient an effective amount of peptide of SEQ ID NO: 8, respectively. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant method,

Art Unit: 1646

thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The nature of the invention as asserted in the instant specification and further supported in the Declaration of Gobron filed on March 24, 2003 is that a peptide of SEQ ID NO: 8 when administered directly to disrupted spinal cord, leads to the improvement of regeneration of nervous tissue in rats. The limited working examples in the specification, as originally filed, pertain to *in vitro* studies of the instant peptides and cell cultures. Thus, as fully explained in the previous office actions of record, the instant specification fails to provide essential information needed by a routine practitioner regarding effective amount, suitable routes and regimes of administration of a peptide of SEQ ID NO: 8, thus requiring undue experimentation.

Moreover, claims 11 and 20, as amended, specifically recite "neuroblastoma" as a pathological condition requiring regeneration of nervous system cells to be treated by the claimed method. A skilled artisan readily understands that addition of a peptide that promotes regeneration of nervous system cells to cancerous neuroblastoma cells appear to contradict the purpose of the treatment by promoting proliferation. The instant specification, as filed, fails to specifically address regime of treatment of neuroblastoma by administration of a pharmaceutical composition comprising a peptide of SEQ ID NO: 8.

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed pharmaceutical composition or the claimed method without first making a substantial inventive contribution.

Art Unit: 1646

9. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 2 and 4 are vague and indefinite because the relationship of “SEQ ID NOS: 50-59” or “SEQ ID NOS: 65-88” and SEQ ID NO: 9 is not obvious and cannot be determined from the claim or the instant specification. Clarification is required.

11. Claims 3 and 5 are indefinite for reasons of record as applied to claim 5 in section 14 of Paper No. 18. Specifically, the metes and bounds of the recitation “60-64” or “and 89-96” cannot be determined from the claim. Applicant is advised that recitation “SEQ ID NOS: 60-64”, for example, would obviate this ground of rejection.

12. Claim 6 is indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

13. Claims 1-6, 8, 13, 16, 17 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gobron et al. for reasons of record in section 16 of Paper No. 18 and section 12 of Paper No. 22. Because of the use of open language in defining the structure of the claimed peptides and because Gobron et al. disclose a fragment of SCO-spondin, which has the amino acid sequence identical to SEQ ID NO: 8 of the instant application and also matches the description of SEQ ID NO: 7 and SEQ ID NO: 9, Gobron et al. anticipate claims 1-6, 8, 13, 16, 17 and 22.

Art Unit: 1646

Applicant traverses the rejection by presenting an explanation that the number of the amino acids of “the claimed peptide has at most a contiguous amino acid chain of 26 residues” (end at page of 15 of the Response). However, on the contrary, the peptide of SEQ ID NO: 9, as recited in claim 1, has terminal ends “Y” and “Z”, “wherein Y and Z comprise”, emphasis added, certain recited molecular embodiments. Thus, nothing in the claim precludes the peptide to comprise more than “amino acid chains consisting less than 6 amino acids”. Therefore, due to the use of open language in claims defining SEQ ID NO: 9 and SEQ ID NOS: 7 and 8, the claimed subject matter is fully anticipated by Gobron et al..

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December


Art Unit: 1646

28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER